

FEB 24 1999



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

Norman H. Stepno
Burns, Doane, Swecker & Mathis, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,212,303 (Sol'n)

#15

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,212,303, which claims a method of manufacturing the human drug product DIFFERIN Solution (adapalene), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 13 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to the requirement for an election may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration and if the above-identified patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 13 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 2, 1997 (62 Fed. Reg. 101). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,651 - 1,651) + 1,163 - 53 \\ &= 1,110 \text{ days}\end{aligned}$$

Since the testing phase regulatory review period began September 18, 1988 and concluded on March 26, 1993, and the approval phase of the regulatory review period began March 26, 1993, which was before the patent issued (May 18, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From March 26, 1993 to May 18, 1993 is days 53; this period is subtracted from the number of days occurring in the approval phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,110 days, would extend the patent from May 18, 2010 to June 1, 2013, which is beyond the 14-year limit

(14 years after the approval date is May 31, 2010). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, May 18, 2010 to and including May 31, 2010, or 13 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Applicant has also filed applications for patent term extension of U.S. Patent Nos. Re. 34,440, 4,717,720, 5,015,758 and 5,212,303, based upon the regulatory review of the product DIFFERIN Gel, and U.S. Patent Nos. Re. 34,440, 4,717,720, 5,015,758 based upon the regulatory review of the product DIFFERIN Solution. DIFFERIN Gel and DIFFERIN Solution have different regulatory review periods. No more than one patent may be extended based upon a regulatory review period of a product. 35 U.S.C. § 156(c)(4). A patent can only be extended once under 35 U.S.C. § 156(e)(1). 35 U.S.C. § 156(a)(2). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby **REQUIRED TO ELECT** a single patent for extension based upon the regulatory review period of DIFFERIN Solution. The same patent cannot also be elected for extension based upon the regulatory review of DIFFERIN Gel. In deciding which patent to elect, applicant should also consider that U.S. Patent Nos. 5,015,758 and 5,212,303 claim the method of manufacturing adapalene and, if either of these patents are elected, applicant would have the rights set forth in 35 U.S.C. § 156(b)(3), but the extended expiration date will not be published in FDA's Orange Book. U.S. Patent No. Re. 34,440 claims the method of use of adapalene and, if elected, applicant would have the rights set forth in 35 U.S.C. § 156(b)(2). U.S. Patent No. 4,717,720 claims adapalene and the method of use of adapalene and if elected, applicant would have the rights set forth in 35 U.S.C. § 156(b)(1) and (2). If the above-identified patent is elected for extension based upon the regulatory review period of DIFFERIN Solution, the Commissioner will issue a certificate of extension, under seal, for a period of 13 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,212,303
Granted	:	May 18, 1993
Original Expiration Date	:	May 18, 2010
Applicant	:	Braham Shroot et al.

Owner of Record : Centre International de Recherches
Dermatologiques

Title : Benzonaphthalene Derivatives, A Process of
Their Preparation and Their Use in
Therapeutic and Cosmetic Compositions

Classification : 544/69

Product Trade Name : DIFFERIN Solution (adapalene)

Term Extended : 13 days

Expiration Date of Extension : May 31, 2010

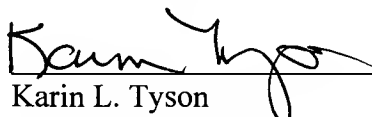
Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at
(703) 306-3159.


Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: DIFFERIN Solution
FDA Docket No.: 96E-0353

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Alexandria, VA 22313-1404

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,212,303 (Gel)

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,212,303, which claims a method of manufacturing the human drug product DIFFERIN Gel (adapalene), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 13 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to the requirement for an election may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration and if the above-identified patent is elected, the Commissioner will issue a certificate of extension, under seal, for a period of 13 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 28, 1997 (62 Fed. Reg. 4064). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,401 - 1,336) + 1,046 \\ &= 1,079 \text{ days}\end{aligned}$$

Since the regulatory review period began September 20, 1989, before the patent issued (May 18, 1993), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From September 20, 1989 to May 18, 1993 is 1,336 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,079 days, would extend the patent from May 18, 2010 to June 2, 2013, which is beyond the 14-year limit (14 years after the approval date is May 31, 2010). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, May 18, 2010

to and including May 31, 2010, or 13 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Applicant has also filed applications for patent term extension of U.S. Patent Nos. Re. 34,440, 4,717,720, and 5,015,758, based upon the regulatory review of the product DIFFERIN Gel, and U.S. Patent Nos. Re. 34,440, 4,717,720, 5,015,758 and 5,212,303 based upon the regulatory review of the product DIFFERIN Solution. DIFFERIN Gel and DIFFERIN Solution have different regulatory review periods. No more than one patent may be extended based upon a regulatory review period of a product. 35 U.S.C. § 156(c)(4). A patent can only be extended once under 35 U.S.C. § 156(e)(1). 35 U.S.C. § 156(a)(2). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby **REQUIRED TO ELECT** a single patent for extension based upon the regulatory review period of DIFFERIN Gel. The same patent cannot also be elected for extension based upon the regulatory review of DIFFERIN Solution. In deciding which patent to elect, applicant should also consider that U.S. Patent Nos. 5,015,758 and 5,212,303 claim the method of manufacturing adapalene and, if either of these patents are elected, applicant would have the rights set forth in 35 U.S.C. § 156(b)(3), but the extended expiration date will not be published in FDA's Orange Book. U.S. Patent No. Re. 34,440 claims the method of use of adapalene and, if elected, applicant would have the rights set forth in 35 U.S.C. § 156(b)(2). U.S. Patent No. 4,717,720 claims adapalene and the method of use of adapalene and if elected, applicant would have the rights set forth in 35 U.S.C. § 156(b)(1) and (2). If the above-identified patent is elected for extension based upon the regulatory review period of DIFFERIN Gel, the Commissioner will issue a certificate of extension, under seal, for a period of 13 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,212,303
Granted	:	May 18, 1993
Original Expiration Date	:	May 18, 2010
Applicant	:	Braham Shroot et al.
Owner of Record	:	Centre International de Recherches Dermatologiques

Title : Benzonaphthalene Derivatives, A Process of
Their Preparation and Their Use in
Therapeutic and Cosmetic Compositions

Classification : 544/69

Product Trade Name : DIFFERIN Gel (adapalene)

Term Extended : 13 days

Expiration Date of Extension : May 31, 2010

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at
(703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: DIFFERIN GEL
FDA Docket No.: 96E-0353